

**REMARKS**

Claims 3-13 are pending. Claims 3 and 6-13 are rejected. Claims 4-5 would be allowable if written in independent form. Upon entry of the current Amendment and Response, claims 3 and 5-15 will be pending.

Applicants amend claim 3 to incorporate the recitations of claim 4. Applicants amend claim 6 to remove the expression "naturally occurring in *Saccharomyces cerevisiae* or *Podospora anserin*." This recitation is presented in new dependent claim 14. Applicants wish to insure that the claim covers recombinant forms of the protein, which may, for example, be over expressed and then purified, as well as naturally occurring forms purified from *Saccharomyces cerevisiae* or *Podospora allserin*. New claim 15 is introduced with specific fragments described expressly in the specification at page 8, line 23, page 12, line 5 and page 12, line 10, respectively.

***Regarding Sequence Listing***

The Examiner indicates that a Sequence Listing in accordance with USPTO formal regulations must be filed. Applicants submit herewith a Sequence Listing in accordance with 37 CFR §1.821(g) in computer readable form and a Statement in Support of the same. The Sequence Listing provides the sequence information for the two primer sequences described on page 8 of the specification.

***Objection to the Claims***

Claim 6 is objected to as not further limiting claim 3 from which it depends. The Examiner seems to suggest that limiting the claim to "said indicator is a purified form naturally occurring in *Saccharomyces cerevisiae* or *Podospora anserina*" would overcome this objection. Applicants herein remove the recitation "or a fungus" as well as reference to the specific species. In view of this amendment as well as the amendments to claim 3, the rejection is overcome.

***Rejection under 35 USC 112, second paragraph***

The Examiner rejects claim 3 because the term "the steps" allegedly does not have proper antecedent basis. Applicants respectfully disagree with the Examiner, however, in the interest of

advancing prosecution, Applicants remove the offending term.

***Rejection under 35 USC 112, first paragraph***

The Examiner rejects claims 3 and 6-13 alleging that the specification only describes the particular fungal prion protein degradation indicator sup35, Ure2p and Het-s so as to satisfy the written description requirement. The Examiner seems to indicate that obtaining broader claims would at a minimum require disclosure of additional indicators (proteins). The Examiner seems to indicate also that even after more indicators (e.g., proteins) were shown, some description of required or common structure that is necessary for particular function would also be required.

*1. Changes to further clarify the invention*

Applicants do not acquiesce that the Examiner's statements represent the current state of the law in the United States as regards written description. Furthermore, whether or not these statements represent the way the USPTO is currently applying the "Written Description Guidelines" issued in 2001 to such protein inventions is not conclusive as to whether such application is legally correct. Nonetheless, in the interest of advancing prosecution and securing swift issuance of a patent, Applicants make some changes to the claims. First, Applicants amend claim 3 so that it does not specify that the indicator is transcribed by a gene naturally occurring in a fungus selected from the group consisting of *Saccharomyces cerevisiae*, and *Podospora anserina*. Applicants submit that describing the indicator as "one transcribed by a gene selected from the group consisting of SUP35, URE2 and HET-s" is supported in the specification and in claim 4 as originally filed. Therefore, no issue of new matter arises by way of this change.

Second, Applicants amend claim 6 to remove the recitation "analog" and to add functional language to describe the recombinant forms, the mutants, and the fragments embraced by the claim language. The functional language "wherein said indicator is insoluble in non-ionic detergents, partly resistant to proteases' action, and forms abnormal amyloid filaments composed of  $\beta$ -sheets" is expressly supported by the specification at page 1, line 31 to page 2, line 5.

*2. The legal standard for determining compliance with the written description requirement*

*The test* for determining compliance with the written description requirement *is whether the disclosure* of the application as originally filed *reasonably conveys* to the artisan *that the inventor had possession* at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. *See, e.g. In re Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983).* The inquiry of whether the written description requirement is satisfied is completely distinct from any inquiry regarding enablement. Applicants respectfully ask the Examiner to again review the "Written Description Guidelines" issued in 2001. The guidelines specifically approve claiming an invention with structural language or a combination of structural and functional language to describe the metes and bounds embraced by the claims. As regards independent claim 3, Applicants provide very specific structural language. As regards dependent claim 6, Applicants add still further descriptive functional language.

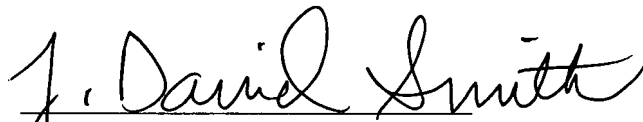
### **FEES**

No additional fees are believed to be necessary. However, if any additional fees are due, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment.

### **CONCLUSION**

Applicants respectfully request entry of the foregoing amendments and remarks in the file of the instant Application. Early and favorable action on the claims is earnestly solicited. If any issues may be resolved by telephone, the Examiner is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

  
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